claims 53-66 have been added, all without prejudice to pursuing canceled subject matter in a continuing application, and without disclaimer of any subject matter.

Support for these amendments may be found throughout the specification and claims as originally filed. Specifically, claim 38 has been amended for the third time to recite that the composition of the claimed method comprises an active component consisting essentially of at least one 1-hydroxy-2-pyridone as defined in the claim. The "consisting essentially" language is intended to exclude those ingredients that would materially change the basic and novel characteristics of the active component in the composition employed by Applicants' claimed method. See MPEP § 2111.03. The composition may still comprise all manner of additives, such as, for example, those described in the specification on page 7, line 36, to page 8, line 16.

Claim 38 has also been amended to incorporate the subject matter of claim 49. Accordingly, claim 49 has been canceled.

Claim 39 has been made independent. The scope of this claim has not changed from what has been examined, since claim 39 now recites the subject matter of former claim 38 (twice amended). Accordingly, support for this change can be found throughout the specification and claims as originally filed.

New claim 53 differs from former claim 38 (twice amended) by reciting that the composition employed by the claimed method comprises at least one keratolytic agent, and has a pH ranging from about 4.5 to about 6.5. Support for this claim language may be found throughout the specification and claims as originally filed, and also in the specification on page 8, lines 5-6 and 29-30. New claims 54-58 depend from claim 53. New claim 59 corresponds roughly to claim 39 as amended, but also recites at least one keratolytic agent. New claims 60-64 depend from Claim 59. Support for claims 53, 54,

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59 and 60 may be found, among other places, in the specification on page 8, lines 5-6. Support for claims 65 and 66 is found generally in the specification and specifically in Example 7 on page 12.

II. Claim Rejections under 35 U.S.C. § 102

A. Dascalu et al.

Claims 38, 40, and 42 have been rejected under 35 U.S.C. § 102(a) as being anticipated by Dascalu et al. (WO 96/29045). See Office Action at page 2. Dascalu et al. allegedly teaches the treatment of "dandruff, seborrheic dermatitis," employing a composition comprising ciclopirox olamine according to Applicants' claims. Id. Applicants respectfully traverse.

Dascalu et al. does not anticipate the rejected claims. Dascalu et al. teaches compositions containing a cytotoxic agent and an antifungal agent. Claim 38 has been amended to recite that a composition according to Applicants' claimed method comprises an active component consisting essentially of at least one 1-hydroxy-2-pyridone of formula I. A cytotoxic agent, required by Dascalu et al., would materially change the basic and novel characteristics of the active component of the composition recited in claim 38. Thus, claim 38 would not read upon a composition employed as taught by Dascalu et al.

In addition, Applicants note that Dascalu et al. misuses dermatology nomenclature by confusing "dandruff" with "seborrheic dermatitis." See Dascalu et al. at page 1 (stating "Dandruff, seborrheic dermatitis of the scalp, is a common disease involving 3-5% of the population.") Although seborrheic dermatitis involving the scalp may give rise to a mistaken diagnosis of dandruff, it is well understood in the field of

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dermatology that seborrheic dermatitis is a condition distinct from dandruff. See Fitzpatrick's Dermatology in General Medicine, 5th ed., CD-ROM, Ch. 126 (1999). Copy attached. Applicants note the date of this document, and do not admit that it is "prior art" to their application.

Despite its misuse of dermatological nomenclature, Dascalu et al. clearly teaches the treatment of dandruff. Applicants claim a method for the treatment of seborrheic dermatitis, which, as noted above, is a distinct condition. For this reason as well, Dascalu et al. does not anticipate the rejected claims.

Applicants also note that claims 53-64 recite that the composition of the claimed method comprises at least one keratolytic agent in addition to at least one 1-hydroxy-2-pyridone. Claims 65 and 66 comprise lactic acid in addition to at least one 1-hydroxy-2-pyridone. Dascalu et al. does not teach or suggest compositions comprising keratolytic agents or lactic acid. Therefore, Dascalu et al. does not anticipate any of Applicant's claims.

Applicants respectfully request that this rejection over Dascalu et al. be withdrawn.

B. Lange

Claims 38, 40-42, and 48-49 have been rejected under 35 U.S.C. § 102(a) as being anticipated by Lange (US 5,132,107). See Office Action at page 3. Lange allegedly teaches "an anti-seborrheic composition comprising an effective amount of piroctone olamine and its utility as anti-dandruff shampoo," in addition to pH levels of 3-6. Id. Applicants respectfully traverse this rejection.

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Lange does not anticipate present claim 38. Lange does not describe a method of treating seborrheic dermatitis employing a composition containing at least one 1-hydroxy-2-pyridone and at least one surfactant at a pH ranging from about 4.5 to about 6.5, as claimed in amended claim 38. Lange discloses a "two phase shampoo . . . especially for controlling dandruff." Lange at Abstract. The phase I composition obtains the best results "with a pH between 7.5 and 8.5." See Lange at col. 3, line 60. Thus, disclosure of the phase I composition does not anticipate Applicants' claimed invention.

Lange's disclosure of the phase II composition does not anticipate claim 38 either. The phase II composition contains no surfactants. See Lange at col. 5, line 14, to col. 6, line 11.

To find a method of treating seborrheic dermatitis as claimed by Applicants requires one of ordinary skill in the art to meander through Lange's disclosure, picking and choosing various items. This method of analysis was rejected in In re Arkley, 172 USPQ 524 (C.C.P.A. 1972). There, the court explained that, to anticipate, a "reference must clearly and unequivocally disclose the claimed [invention] or direct those skilled in the art to the [invention] without any need for picking, choosing, and combining various disclosures not directly related to each other by the teachings of the cited reference." 172 USPQ at 526. See also MPEP § 2131.

New claims 53-66 are also not anticipated. Lange does not describe the methods of treating seborrheic dermatitis employing a composition containing at least one 1-hydroxy-2-pyridone and at least one surfactant at a pH ranging from about 4.5 to about 6.5, as claimed in new claims 53 to 59. Also, the particular 1-hydroxy-2-pyridones of claims 56 and 63 find no mention nor suggestion in Lange.

Applicants respectfully request that this rejection be withdrawn.

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C. Thorel

Claims 38, 40-42, and 48-49 have been rejected under 35 U.S.C. § 102(a) as being anticipated by Thorel (FR 2694694). See Office Action at page 3. However, the Office Action provided Applicants with a different French patent, also to Thorel, FR 2685867(Thorel '867), with the Form PTO 892. The Office Action at page 3 seems to cite to page 9, line 29, of this '867 Thorel patent. Assuming that the rejection is based on Thorel '867, Applicants address their remarks to this document. For the Examiner's convenience, Applicants enclose an English-language translation of Thorel '867.

Thorel '867 allegedly teaches 1-hydroxy-2-pyridone derivatives such as piroctone olamine as an effective active agent for treating seborrheic dermatitis. Office Action at page 3. Applicants respectfully traverse this rejection.

Thorel '867 does not describe Applicants' method of amended claim 38. Thorel '867 describes, among other things, compositions containing a 1-hydroxy-2-pyridone having certain substituents, and a undecylenic acid derivative. See Thorel '867 at Abstract. Applicants' claim 38 has been amended to recite that the composition of the claimed method comprises an active component consisting essentially of at least one 1-hydroxy-2-pyridone. Since the undecylenic acid derivative of Thorel '867 would materially change the basic and novel characteristics of the active component of the composition employed by Applicants' claimed method, claim 38 does not read on the method described by Thorel '867.

Moreover, Thorel '867 does not describe, teach, or suggest the method claimed in new claims 53-66, either. For example, Thorel '867 does not teach or suggest keratolytic agents or lactic acid. Therefore, the compositions taught by Thorel '867 do not anticipate the Applicant's claims.

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Applicants therefore request that this rejection be withdrawn.

D. Saint-Leger

Claims 38, 40-42, and 48 have been rejected under 35 U.S.C. § 102(e) as being anticipated by Saint-Leger (US 5,650,145). See Office Action at page 3. Saint-Leger allegedly teaches 1-hydroxy-2-pyridones such as Ciclopirox or Octopirox as effective for treating seborrheic dermatitis, as well as surfactants. See id. Applicants respectfully traverse this rejection.

Saint-Leger discloses a composition for treating human hair loss, comprising an antifungal agent and a halogenated antibacterial agent. See Saint-Leger at Abstract. Present claim 38 now recites that the composition employed by Applicants' method comprises an active component consisting essentially of at least one 1-hydroxy-2-pyridone. By requiring a halogenated antibacterial agent, Saint-Leger does not describe Applicants' method of treating seborrheic dermatitis as claimed in claim 38.

Saint-Leger also does not describe Applicant's method claimed in claims 53-66. These claims recite that the composition of the claimed method comprises at least one keratolytic agent or lactic acid. Saint-Leger does not teach or suggest a composition comprising keratolytic agents or lactic acid. Therefore, Saint-Leger does not anticipate any of Applicant's pending claims.

Applicants respectfully request that this rejection be withdrawn.

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E. Rivalland et al.

The Rivalland et al. abstract is cited in support of one or more of the above rejections under 35 U.S.C. § 102, for the proposition that "the therapeutic effects of [1-

hydroxy-2-pyridone] alone is also well documented and evidenced by Rivalland." Office Action at page 3, referring to Rivalland et al., "Evaluation of the Antifungal Activity of Two Derivatives and *In Vivo* Innocuity Test of Shampooings with Regard to Antidandruff Formulations," Abstract, Int. J. Cosmet. Sci. (1994), Vol. 16(2), pages 77-83. Applicants note that this abstract nowhere mentions treating seborrheic dermatitis.

Applicants again point out the distinction between "dandruff" and "seborrheic dermatitis." See Fitzpatrick's Dermatology in General Medicine, 5th ed., CD-ROM, Ch. 126 (1999) (copy attached). Since the Rivalland et al. abstract mentions only "dandruff," this document does not anticipate the claimed invention.

III. Claim Rejections under 35 U.S.C. § 103

Claim 39 has been rejected under 35 U.S.C. § 103(a) as being unpatentable over Dittmar et al. (US 4,185,106) in view of Dascalu et al. and Saint-Leger. See Office Action at page 4. The Office Action recognizes that claim 39 may be distinguished over the cited documents. First, claim 39 requires "the specific bicyclic substituents," in the words of the Office Action. Second, claim 39 requires seborrheic dermatitis. See Office Action at page 4. Dittmar et al. teaches treatment of dandruff, which is distinct from seborrheic dermatitis. Nonetheless, the Office Action concludes that it would be within the skill of those of ordinary skill in the art to obtain the subject matter of claim 39, given the teachings of the cited documents. Applicants respectfully traverse this rejection.

35 U.S.C. § 103 authorizes a rejection where to meet the claim, it is necessary to modify a single reference or to combine it with one or more other references. To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in

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the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. See, M.P.E.P. 706.02(j). The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on the applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

The references cited by the Examiner fail to teach or suggest all of the elements of Claim 39. Claim 39 recites that "Ar is a bicyclic system derived from biphenyl, diphenylalkane, or diphenyl ether." This bicyclic system is not taught or suggested in any of the three cited documents. As the Examner has noted, Dittmar differs from Applicant's claim in that Applicant's claim requires "specific bi-cyclic substituents in the R^4 position See Office Action at 4. Neither Dascalu et al. nor Saint-Leger teach or suggest this missing element. Since none of the cited references teach or suggest this element of claim 39, the requirements of 35 U.S.C. § 103 have not been met and the Applicants respectfully request that this rejection be withdrawn. See MPEP § 2143.03

CONCLUSION

In view of the foregoing remarks, Applicants respectfully request the reconsideration of this application and the timely allowance of the pending claims.

A Petition for Extension of Time (Three Months) and fee accompany this Amendment. Please grant any further extensions of time required to enter this response and charge any additional fees required therefor to our Deposit Account No. 06-0916.

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Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: April 24, 2002

By: Jeremy M. Stipkala by
Jeremy M. Stipkala
Reg. No. 44,359 Carol P. Evans
Reg. No. 32,220

Enclosures:

- 1. Translation of Thorel (FR 2685867)
- 2. Fitzpatrick's Dermatology in General Medicine, 5th ed., CD-ROM, Ch. 126 (1999).

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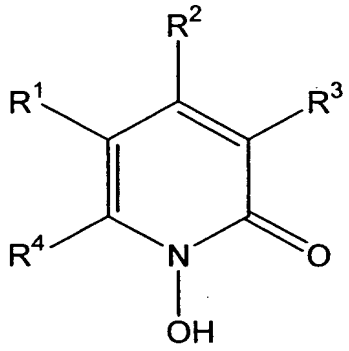
APPENDIX

In accordance with 37 C.F.R. § 1.121(c), the amended claims are set forth below in marked-up form to aid the Examiner in identifying amendments to the claims. Additions are underlined, and deletions are shown with bold square brackets and strikethrough font **[~~like this~~]**.

38. (Thrice Amended) A method of treating a human or animal patient in need of treatment for seborrheic dermatitis comprising administering to the patient an amount effective for the treatment of seborrheic dermatitis of a composition comprising:

(A) an active component consisting essentially of at least one 1-hydroxy-2-pyridone of formula I, wherein the at least one 1-hydroxy-2-pyridone is present in free form or as a pharmaceutically acceptable salt:



(I)

where R^1, R^2, and R^3, which are identical or different, are H or alkyl having 1 to 4 carbon atoms, and R^4 is a saturated hydrocarbon radical having 6 to 9 carbon atoms or a radical of formula II:

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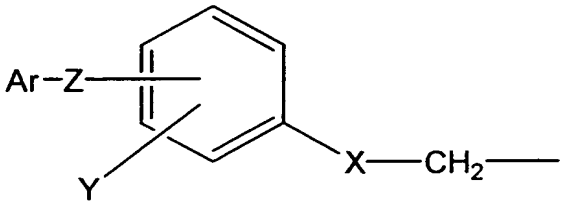

(II)

where:

X is S or O;

Y is H, or 1 or 2 identical halogen atoms, or a mixture of 2 different halogen atoms;

Z is a single bond, or

a linking radical comprising

(1) O, or

(2) S, or

(3) $-CR_2-$, where R is H or (C_1-C_4)-alkyl, or

(4) from 2 to 10 carbon atoms linked in the form of a straight or branched chain, which optionally further comprises one or more of the following:

(i) a carbon-carbon double bond, and

(ii) O, S, or a mixture thereof, wherein if 2 or more O or S atoms or a mixture thereof are present, each O or S atom is separated by at least 2 carbon atoms; and,

in any of the foregoing linking radicals, any remaining free valences of the carbon atoms of said linking radical are saturated by H, (C_1-C_4)-alkyl, or a mixture thereof;

and

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Ar is an aromatic ring system having one or two rings, the aromatic ring system being unsubstituted or substituted by one, two, or three radicals, which are identical or different, and are chosen from halogen, methoxy, (C_1-C_4)-alkyl, trifluoromethyl, and trifluoromethoxy; and [~~,~~

~~wherein the at least one 1-hydroxy-2-pyridone of formula I is administered to the patient in a pharmaceutical composition, the pharmaceutical composition further comprising~~]

(B) at least one surfactant chosen from anionic surfactants, cationic surfactants, nonionic surfactants, and amphoteric surfactants; and

wherein the composition has a pH ranging from about 4.5 to about 6.5.

39. (Twice Amended) A method of treating a human or animal patient in need of treatment for seborrheic dermatitis [~~as claimed in claim 49 in which the 1-hydroxy-2-pyridone of formula I comprises Ar as~~]

comprising administering to the patient an amount effective for the treatment of seborrheic dermatitis of a composition which comprises:

(A) at least one 1-hydroxy-2-pyridone of formula I, wherein the at least one 1-hydroxy-2-pyridone is present in free form or as a pharmaceutically acceptable salt:

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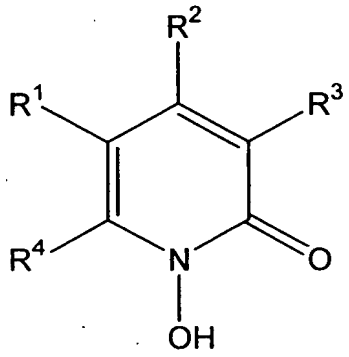
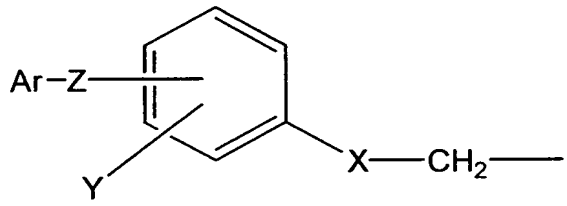


(I)

where R^1, R^2, and R^3, which are identical or different, are H or alkyl having 1 to 4 carbon atoms, and R^4 is a saturated hydrocarbon radical having 6 to 9 carbon atoms or a radical of formula II:



(II)

where:

X is S or O;

Y is H, or 1 or 2 identical halogen atoms, or a mixture of 2 different halogen atoms;

Z is a single bond, or

a linking radical comprising

(1) O, or

(2) S, or

(3) $-CR_2-$, where R is H or (C_1-C_4)-alkyl, or

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(4) from 2 to 10 carbon atoms linked in the form of a straight or branched chain, which optionally further comprises one or more of the following:

(i) a carbon-carbon double bond, and

(ii) O, S, or a mixture thereof, wherein if 2 or more O or S atoms or a mixture thereof are present, each O or S atom is separated by at least 2 carbon atoms; and,

in any of the foregoing linking radicals, any remaining free valences of the carbon atoms of said linking radical are saturated by H, (C_1-C_4)-alkyl, or a mixture thereof;

and

Ar is an aromatic ring system having two rings, the aromatic ring system being unsubstituted or substituted by one, two, or three radicals, which are identical or different, and are chosen from halogen, methoxy, (C_1-C_4)-alkyl, trifluoromethyl, and trifluoromethoxy, and wherein Ar is a bicyclic system derived from biphenyl, diphenylalkane, or diphenyl ether; and

(B) at least one surfactant chosen from anionic surfactants, cationic surfactants, nonionic surfactants, and amphoteric surfactants.

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